An observational cohort study to evaluate the risk of adverse pregnancy outcomes in patients treated with etanercept compared to those not treated with etanercept or other biologics using merged data from Sweden, Denmark and Finland

First published: 13/08/2017
Last updated: 01/04/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/25620

EU PAS number
EUPAS20081

Study ID
25620

DARWIN EU® study
No

Study countries
Denmark
Finland
Sweden

Study description
This is a population-based study of data from the national health registers of Sweden, Denmark and Finland. The study will compare the rate of adverse outcomes, including birth defects, preterm birth, small for gestational age and infections in infancy among infats to

women exposed to etanercept with infants to women not exposed.

Study status
Finalised

Research institution and networks

Institutions

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden
First published: 24/03/2010
Last updated
23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Department of Clinical Epidemiology Aarhus University, Aarhus, Denmark, National Institute for Health and Welfare Helsinki, Finland

Contact details

Study institution contact
Helle Kieler
Study contact

helle.kieler@ki.se
Primary lead investigator
Helle Kieler
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
01/07/2017
Actual:
01/07/2017

Study start date
Planned:
01/07/2006
Actual:
01/07/2006

Data analysis start date
Planned:
01/07/2017
Actual:
01/07/2017

Date of final study report
Planned:
31/12/2018
Actual:
02/07/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

Enbrel PASS protocol_B1801396_v 3.pdf(1.05 MB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type list

Study topic:
Disease /health condition
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:
Secondary data collection

Main study objective:
To compare the risk of adverse birth outcomes in women exposed to etanercept during pregnancy to those not exposed.

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Medical condition to be studied
Rheumatoid arthritis
Psoriasis
Ankylosing spondylitis

Population studied

Short description of the study population
Pregnant women with diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA) or ankylosing spondyloarthritis (AS); for the etanercept treated cohort women who had any treatment with etanercept within 3 months prior to the first day of the last menstrual period (LMP) or any time during pregnancy were included.

Age groups
Preterm newborn infants (0 – 27 days)
Term newborn infants (0 – 27 days)
Infants and toddlers (28 days – 23 months)

Special population of interest
Pregnant women

Estimated number of subjects
1300000

Study design details

Outcomes
Major congenital malformations, Any congenital malformation, preterm birth, small for gestational age, infant infections

Data analysis plan
All birth in Sweden, Denmark and Finland between July 2006 and 2013 will be included. Birth outcomes for infants born to women with etanercept treatment will be compared to those without.

Documents

Study results
Final report for PASS study B1801396 version 3.0 final.pdf(1.65 MB)

Study report
Appendix Final report for Etanercept PASS study B1801396_ version 3.0_Final.pdf(2.22 MB)

Data management

Data sources

Data source(s)
Danish registries (access/analysis)
National Prescribed Drugs Register / Läkemedelsregistret

Data sources (types)
Drug dispensing/prescription data
Other

Data sources (types), other
Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping
No

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
Unknown